THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 32

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte JOHN T. HUNT

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Appeal No. 96-3861
Application 08/114,251[1]

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ON BRIEF

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Before WINTERS, GRON and LORIN, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 2 through 15, which are all of the claims pending in this application.

A copy of Claim 2, which is illustrative of the subject matter on appeal, is appended to this decision.

[1] Application for patent filed August 30, 1993.

In rejecting the appealed claims on non-prior art grounds, the examiner relies on the following references:

M. Clozel, et al., "Pathophysiological role of endothelin revealed by the first orally active endothelin receptor antagonist", Nature, Vol. 365, October 21, 1993, pgs. 759-61. (Clozel)

S. Mihara, et al., "The endothelin ET_A receptor-speciific effect of 50-235, a nonpeptide endothelin antagonist", European Journal of Pharmacology-Molecular Pharmacology Section, Vol. 246, 1993, pgs. 33-38. (Mihara)

A. Doherty, "Endothelin:A New Challange", Journal of Medicinal Chemistry, Vol. 35, No. 9, May 1, 1992, pgs. 1493-1508. (Doherty)

P. D. Stein, et al., "The Discovery of Sulfonamide Endothelin Antagonists and the Development of the Orally Active ET_A Antagonist 5-(Dimethylamino)-*N*-(3,4-dimethyl-5-isoxazolyl)-1-Naphthalensulfonamide, Journal of Medicinal Chemistry, Vol. 37, No. 3, February 4, 1994, pgs. 329-331. (Stein)

The issue presented for review is whether the examiner erred in rejecting claims 2 through 15 under 35 U.S.C. § 112, first paragraph, as based on a non-enabling disclosure.

On consideration of the record, including the appeal brief (paper no. 13) and the Examiner's Answer (paper no. 14), we shall reverse this rejection.

DISCUSSION

The examiner's rejection is couched in terms of 35 U.S.C. § 112, first paragraph. The real issue, however, is whether all of the claimed compounds are useful for treating

hypertension as stated in the specification, paragraph bridging pages 8 and 9. We have no doubt that the specification imparts adequate information to persons skilled in the art, enabling them to make the claimed compounds and to use the claimed compounds as antihypertensive agents if those compounds are useful for the stated purpose. Respecting the "how-to-use" requirement of 35 U.S.C. § 112, first paragraph, the specification sets forth in detail dosage ranges, modes of administration, and pharmaceutically acceptable carriers, applicable for the claimed compounds. The specification also describes numerous other compounds and agents which may be formulated with or useful in conjunction with the claimed compounds.

Turning to the issue at hand, we find this statement in the specification, paragraph bridging pages 8 and 9:

> The compounds of formula 1 are antagonists of ET-1, ET-2, and/or ET-3 and are useful in treatment of all endothelin-dependent disorders. They are thus useful as antihypertensive agents. By the administration of a composition having one (or a combination) of the compounds of this invention, the blood pressure of a hypertensive mammalian (e.g., human) host is reduced.

According to Appellant, all of the claimed compounds are useful for treating hyper-tension, i.e., for reducing blood pressure in a mammalian host.

As stated in In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971),

> It is incumbent upon the Patent Office, whenever a rejection on this basis [lack of enablement] is made, to explain why it doubts the truth or accuracy or any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.

Here, the examiner relies on Clozel, Mihara, Doherty and Stein as evidence casting doubt on the truth or accuracy of Appellant's statement in the specification that all of the claimed compounds are useful for treating hypertension. We disagree with the examiner's analysis.

The references relied on by the examiner establish that endothelin was discovered in 1988; that, since its discovery, there have been many advances pertaining to the development of endothelin receptor antagonists for treating a variety of mammalian diseases; but that many questions remain. Generally speaking, there is a measure of unpredictability in this art as evidenced by Mihara's discussion of 27-O-caffeoyl myricerone (50-235). Note Mihara's statement that the in vivo effect of 50-235 on reducing blood pressure was "less potent than expected" from its in vitro activity (Mihara, page 38, column 1, line 4). The compound 50-235 is not closely related structurally to the claimed compounds.

The examiner does not, however, establish that unpredictability in this art extends to the specific type of compounds claimed. The claimed compounds are naphthyl or biphenyl sulfonamides having a diazine group attached to the nitrogen atom of the sulfonamide. On this record, the examiner has not furnished evidence casting doubt on the truth or accuracy of Appellant's statement that those compounds are useful for treating hypertension. On the contrary, the prior art relied on by the examiner seems to indicate that compounds of the type claimed are predictably effective. See the second paragraph, last sentence of Stein, which states:

> Proof that ET [endothelin] is a causative agent [of diseases] has remained elusive, but the recent discovery of ET receptor antagonists will surely remedy this situation. (emphasis added)

In the ensuing paragraph, Stein refers to a number of endothelin antagonists including "N-pyrimidinylbenzenesulfonamides" recently discovered by Clozel. Note in particular that compound Ro 46-2005 of Clozel, like the claimed compounds, is an aromatic sulfonamide having a diazine group attached to the nitrogen atom of the sulfonamide. According to Clozel, Ro 46-2005 is "the first orally active endothelin receptor antagonist."

For the reasons set forth in the body of this opinion, we believe that: (1) the examiner has not provided adequate evidence casting doubt on the truth or accuracy of Appellant's statement in the specification that all of the claimed compounds are useful for

treating hypertension; and (2) the greater weight of the evidence on this record favors patentability.

The examiner's decision is reversed.

REVERSED

SHERMAN D. WINTERS Administrative Patent Judge	)	
TEDDY S. GRON Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
HUBERT C. LORIN Administrative Patent Judge	)	

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